

Social Media, Rx Promotion, & FDA



Results of a survey of
readers & followers of
Pharma Marketing News,
Pharma Marketing Blog,
and @pharmaguy



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Survey Overview

📍 Online — started 20 September 2009

📍 Includes All 19 questions for which FDA seeks answers

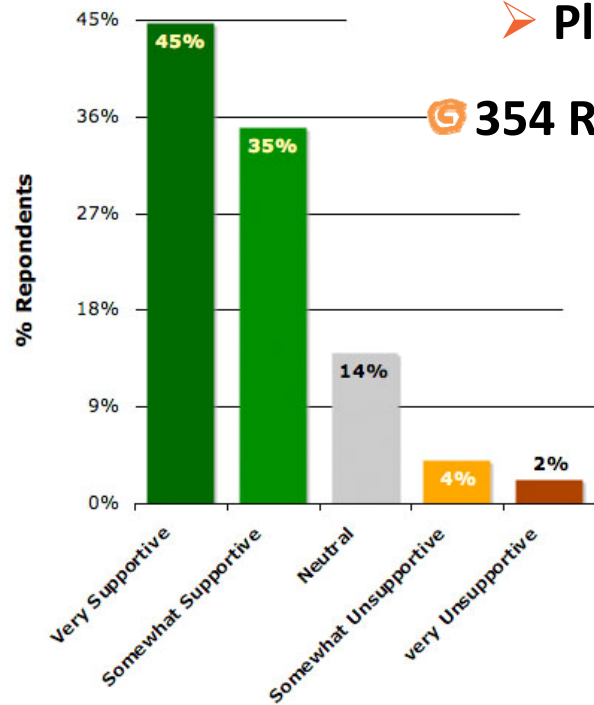
➤ Tallies votes on specific answers/solutions

➤ Plus 575 comments

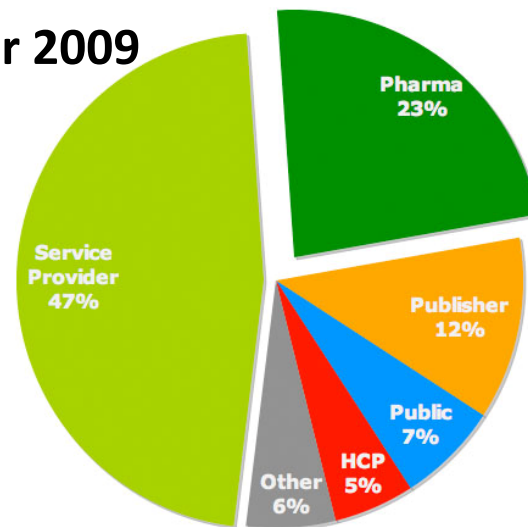
📍 354 Respondents as of 1 November 2009

- 126 Blog readers
- 101 PMN subscribers
- 64 Twitter followers
- 45 Web site visitors

Support of Drug Industry



Respondent Affiliations



Part 2

Adverse Event Reporting

Adverse Events: Summary of Findings

- ⌚ Vast majority of “Adverse Experiences” reported on social media sites do NOT meet the requirements for AE reporting
 - Great majority of respondents (up to 87%) agree*
- ⌚ Although there are monitoring tools available, the resources required to monitor all social media sites for adverse events are not justifiable
- ⌚ Consequently, few companies have standard operating procedures for processing adverse event information from social media sites
- ⌚ However, pharma companies can help consumers report adverse events directly to the FDA using social media tools such as **widgets** placed on drug.com Web sites ([see slide # 9](#)).

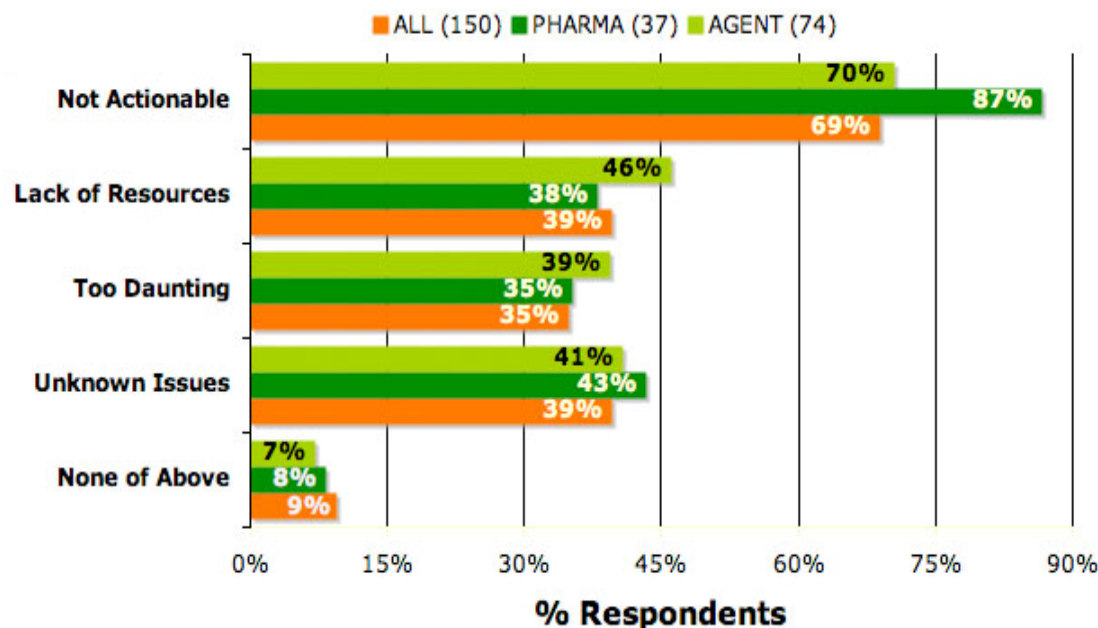
* See slide #5

Social Media AE Challenges

Adverse Event Reporting

What challenges are presented in handling adverse event information from these sources?

- Ⓢ The amount of information from these sources is potentially too vast to be processed economically (**lack of resources**)
- Ⓢ Finding adverse event information from these sources is like finding a needle in a haystack (**too daunting**)
- Ⓢ The information is usually incomplete and does not meet the requirements for submitting a meaningful AER (**not actionable**)
- Ⓢ There are many potential issues that won't fully be known until the practice of monitoring social media for AEs is more prevalent (**unknown issues**)

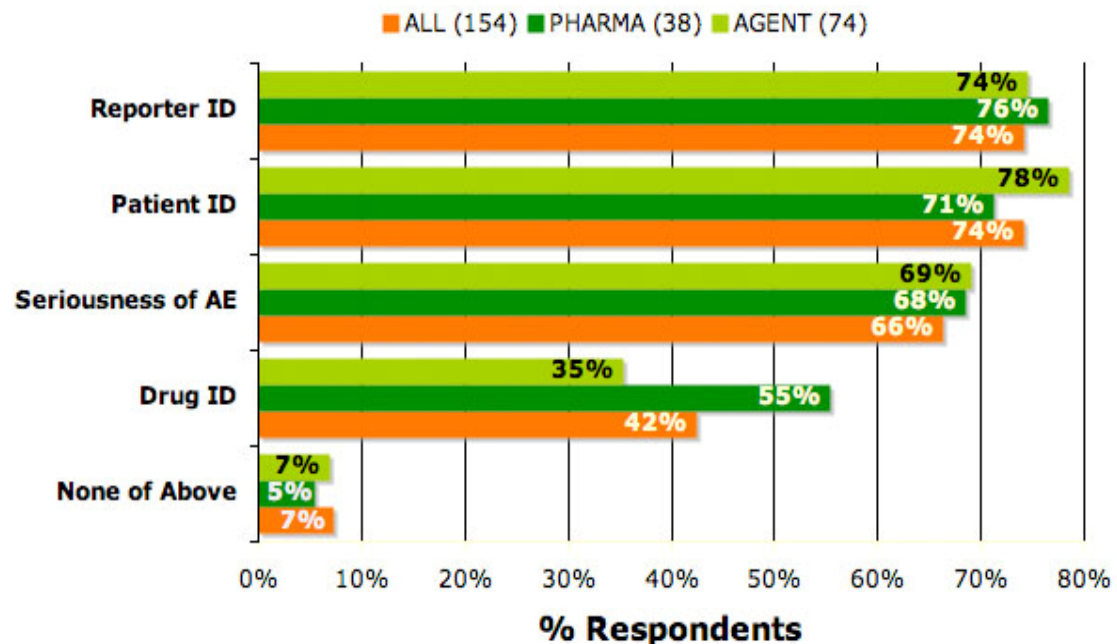


Social Media AE Uncertainties

Adverse Event Reporting

What uncertainties are there regarding what should be reported from these sources to meet FDA adverse event reporting obligations?

- Ⓢ Uncertainty regarding the true identity of the reporter (**anonymous source**)
- Ⓢ Uncertainty regarding the true identity of the patient (**no patient named**)
- Ⓢ Uncertainty regarding the **identity of the drug** (eg, reporter refers to "sleep pill" rather than brand name of drug)
- Ⓢ Uncertainty regarding the **seriousness of the event** reported

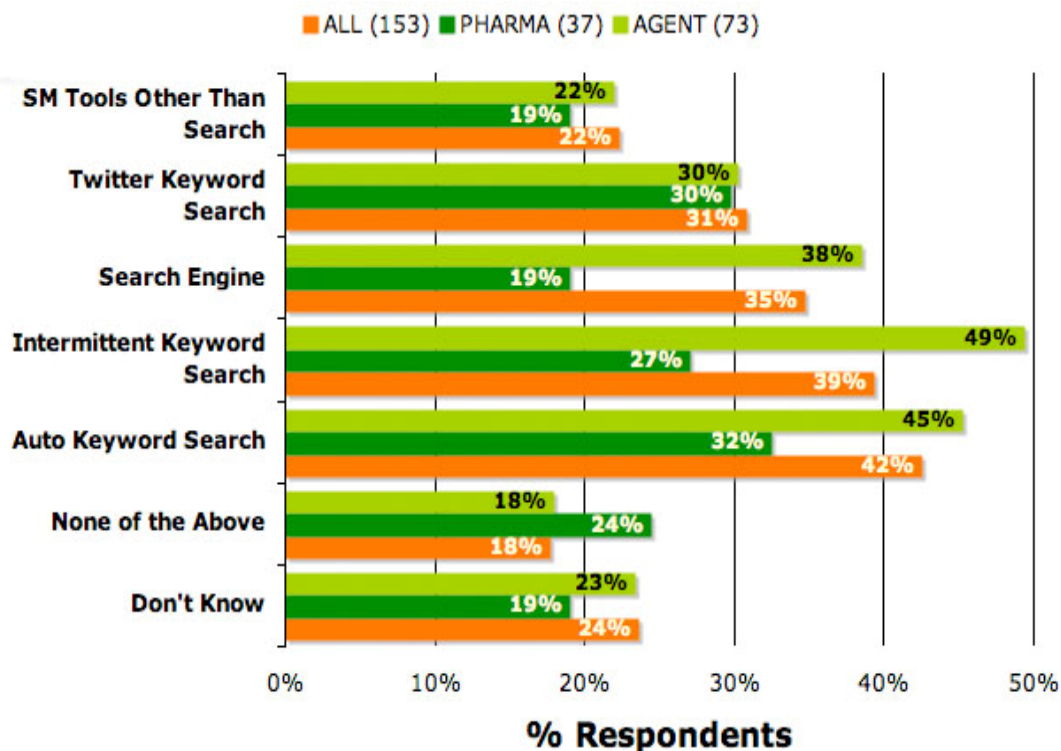


Monitoring AEs on Social Media Sites

Adverse Event Reporting

How are entities with postmarketing reporting responsibilities and other stakeholders using the Internet and social media tools with regard to monitoring adverse event information about their products?

- ⑤ Use of **automated keyword searches** of selected social media sites by specialized agencies and/or professionals
- ⑤ **Intermittent searches** of selected social media sites performed by company personnel or agents
- ⑤ Intermittent searches of **SEARCH ENGINES** performed by company personnel or agents
- ⑤ Routine and automated keyword **searches of TWITTER** (eg, performed by SocialOomph or other services)
- ⑤ Use of **social media monitoring tools** that do not include keywords

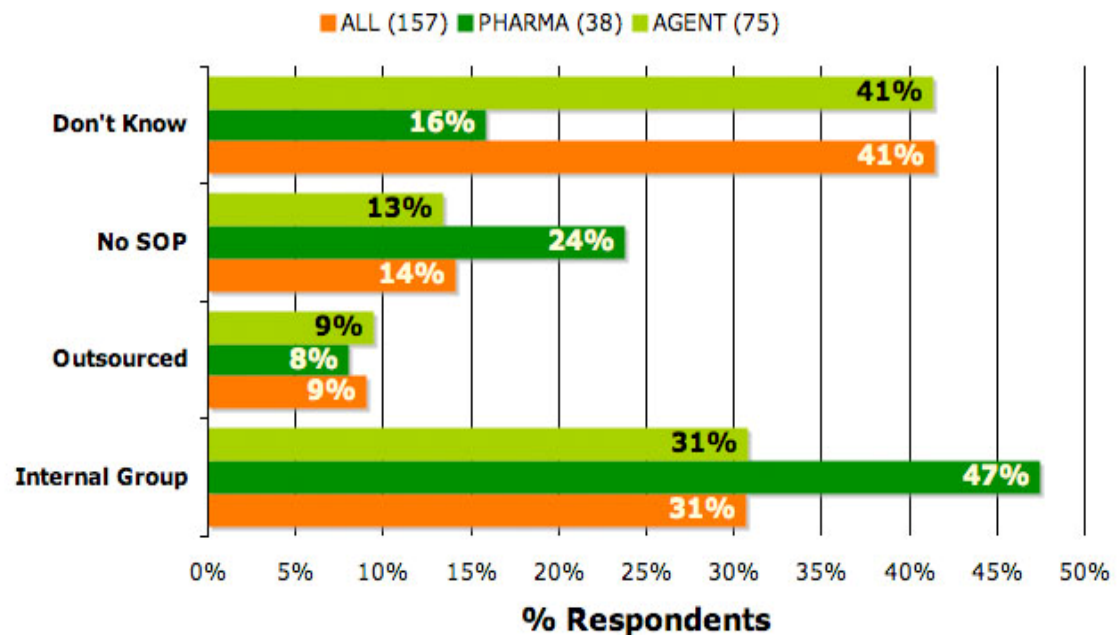


Processing Social Media AE Information

Adverse Event Reporting

How is adverse event information from these sources being received, reviewed, and processed?

- Special group within the company is responsible for receiving, reviewing, and processing AEs
- Receiving and processing AEs is outsourced to a specialized agency; review is handled in-house to determine which AEs need to be reported as required by law
- We have no SOP (Standard Operating Procedure) for receiving, reviewing, and processing AEs from these sources



AE Reporting Safe Harbor Widget

“One-Click” Access to FDA and/or Pharmaco AE Reporting System

ARICEPT
donepezil HCl

Home | Learn About Alzheimer's | Visiting the Doctor | About ARICEPT | On ARICEPT: What to Expect | How ARICEPT is Thought to Work | Side Effects | Health Insurance & ARICEPT | Questions & Answers | Caregiving Tips | Get Support | Tools & Downloads

HOW ARICEPT is Thought to Work

In the Brain

When someone has Alzheimer's disease, nerve cells and other chemicals in the brain are lost over time. This causes a part of the brain that is key to memory and other mental processes. One such chemical is called acetylcholine. This chemical helps carry messages from nerve cell to nerve cell in the brain. Alzheimer's may impair thinking and memory by disrupting these messages between cells.

It is thought that ARICEPT may help reduce the breakdown of acetylcholine, allowing more of this important chemical to remain in the brain.

How the Brain Works

FDA Safety Watch

If you or someone you know are experiencing an adverse event (side effect) as a result of taking your medication, click here for more information.

CLICK HERE

This banner is a universal banner required by all drug manufacturers on their websites. To learn more, click here.

FDA Safety Watch

[Sign up for consumer updates via e-mail](#) | [If you are a healthcare professional, click here](#)

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to talk to your doctor first. Your health care provider can provide clinical information based on your medical record that can help us evaluate your report. Below are 4 options for proceeding:

- Complete a simple online form** which you can then print out and discuss what you are experiencing with your doctor.
- Contact Pfizer at 1-800-438-1985**
Call the FDA at 1-800-FDA-1088
- Download a copy of the form** and either fax it to us at 1-800-FDA-0178 or mail it back using the postage-paid addressed form.
- Complete the MedWatch Online Voluntary Reporting Form and Submit Online**

[Download "Your Guide to Reporting Problems to the FDA"](#)

[Watch Video "MedWatch: Reporting Adverse Events"](#)

Outside the United States
To report a side effect, contact your local health authority or ask your health care provider for more information. Countries worldwide have unique processes in place to handle reports of side effects.

Pharmaceutical companies that post **approved widgets** on their drug.com Web sites should be allowed to monitor 3rd-party social media sites without the need to report any potential adverse events they may come across.

On Sale Outside or Online



*Hoping for Helpful
Guidelines, but Not
Expecting Any*

Availability: In stock. Usually ships within 24 hours.

Order and pay for this T-shirt now using your credit card...
ONLY \$29.95

[Add to Cart](#)

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Contact Information

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**WANTED: Answers to FDA's Q's
Regarding Pharma's Use of Social Media**

**Pharma
Marketing News**
Questionnaire
& Survey

Say what's on your mind! Anonymous
comments welcome! Results will be
submitted to the FDA.

<http://bit.ly/zPR1f>

The advertisement features a green header with white text, a yellow banner with red and black text, and a white background with black text. It includes icons for YouTube, RSS, and the FDA logo, along with a hand holding a pen and a checklist.